

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DAVIS et al

Atty. Ref.: 620-301

Serial No. Div. of Serial No. 09/897,412

Group: Unassigned

Filed: April 13, 2004

Examiner: Unassigned

For: USE OF SECRETIN-RECEPTOR LIGANDS IN  
TREATMENT OF CYSTIC FIBROSIS (CF) AND CHRONIC  
OBSTRUCTIVE PULMONARY DISEASE (COPD)

\* \* \* \* \*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

April 13, 2004

Sir:

**INFORMATION DISCLOSURE STATEMENT**

- ☒ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**  
[within 3 months of filing or prior to 1st Office Action on the merits]  
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
N/C
- ☐ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**  
[after Final Office Action or Allowance (requires Rule 97(e)  
Statement and Rule 17(p) fee), but before final fee payment]  
\$180.00

The following are submitted in the above-identified application in compliance with 37 C.F.R. §§ 1.97 and 1.98:

- ☒ 4. A list of documents on Form PTO-1449 together with copies of each identified document and a translation or a concise explanation of each non-English language document (such as a Search Report) is enclosed herewith. Copies of the cited documents are not believed to be required as the same are of record in the parent Application Serial No. 09/897,412. The Examiner is requested to advise the undersigned however if further copies of the cited documents are required.


This paper is submitted in accordance with:

- ☒ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☐ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
- ☐ a) The required Statement made in item 8 below; or
- ☐ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
- ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
- ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
- ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
- ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information

contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

Respectfully submitted,  
NIXON & VANDERHYE P.C.

By:   
B. J. Sadoff  
Reg. No. 36,663

BJS:pp  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100

**INFORMATION DISCLOSURE  
CITATION**

(Use several sheets if necessary)

ATTY. DOCKET NO.

620-301

APPLICANT

DAVIS et al

FILING DATE

April 13, 2004

SERIAL NO.

Div. of Serial No. 09/897,412

GROUP

Unassigned

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,428,015	06/1995	KURONO, et al			
	3,833,722	09/1974	GRAYBILL			
	6,498,143 B1	12/2002	Beck & Horvath			
	6,020,310	02/2000	Beck & Horvath			
	2002/0099023 A1	07/2002	Boucher			

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	U.S. Equivalents	
					YES	NO
0 150 760	08/1985	EP				
WO 98/02453	01/1998	WIPO				
WO 95/06724	03/1995	WIPO				
WO 95/27496	10/1995	WIPO				

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Marinelli et al, Secretin Promotes Osmotic Water Transport in Rat Cholangiocytes..., The Journal of Biological Chemistry, Vol. 272, No. 20, Issue of May 16, 1197, pp. 12984-12988
	Kanno et al. (September 2001) "Regulation of cholangiocyte bicarbonate secretion." Am. J. Physiol. Gastrointest. Live. Physiol 281(3): G612-G-625
	Tietz et al. (30 May 2003) "Agonist-induced Coordinated Trafficking of Functionally Related Transport Proteins for Water and Ions in Cholangiocytes." The Journal of Biological Chemistry 278(22): 20413-20419
	Windstetter et al. (30 October 1997) "Renal Function and Renotropic Effects of Secretin in Cystic Fibrosis." Eur. J. Med. Res. 2(10): 431-436

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

620-301

Div. of Serial No. 09/897,412

APPLICANT

DAVIS et al

(Use several sheets if necessary)

FILING DATE

GROUP

April 13, 2004

Unassigned

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,020,314	02/2000	McMichael			

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	U.S. Equivalents	
							YES	NO
		WO 97/33616	09/1997	WIPO				
		WO 98/52593	11/1998	WIPO				
		WO 99/64059	12/1999	WIPO				

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Gespach et al, Peptides, Vol. 7, Suppl. I, 155-163 (1986) "Secretin Receptor Activity in Rat Gastric Glands. Binding Studies, cAMP Generation and Pharmacology"
	Mutt et al, Eur. J. Biochem. 15, (1970) 513-519 "Structure of Porcine Secretin"
	Mutoh et al, Proc. Natl. Acad. Sci. Vol. 94, 3560-3564 (1997) Biochemistry "The basic helix-loop-helix transcription factor BETA2/NeuroD is expressed in mamalian enteroendocrine cells and activates secretin gene expression"
	Mutoh et al, Genes & Development 12:820-830 (1998) "The basic helix-loop-helix protein BETA2 interacts with p300 to coordinate differentiation of secretin-expressing enteroendocrine cells"
	Chang et al, The J. of Biological Chemistry, Vol. 274, No. 16, 10758-10764 (1999) "Porcine Pancreatic Phospholipase A <sub>2</sub> Stimulates Secretin Release from Secretin-producing Cells"
	Chang et al, Am. J. Physiol. 275 (Gastrointest. Liver Physiol. 38) G192-G202 (1998) "Modulation of secretin release by neuropeptides in secretin-producing cells"
	Sexton, Current Opinion in Drug Discovery and Development, Vol. 2(5), 440-488 (1999) "Recent advances in our understanding of peptide hormone receptors and RAMPS"
	Stern et al, J. Royal College of Physicians of London, Vol. 33, No. 5, 434-439 (1999) "The pathogenesis of cystic fibrosis and progress towards gene therapy"
	Cross et al et al, Life Sciences, Vol. 29, 895-902 (1981) "Synthesis, Biological and Immunochemical Properties o Analogues of Secretin and Vasoactive Intestinal Peptide (VIP): The Vasectrins
	Fortner et al, Am. J. Physiol. Lung Cell Mol Physiol 280: L334-L341 (2001) "Chloride channel function is linked to epithelium-dependent airway relaxation"
	Wolf et al Chest, 89, 3, 327-330 (1986) "Demonstration of calcitonin and calmodulin by immunoperoxidase in the cystic fibrosis lung"
	Chang et al, AJP-Gastrointestinal and Liver Physiology Abstract Vol. 279, Issue 2, G295-G303 (2000) "Cellular mechanism of sodium oleate-stimulated secretion of cholecystokinin and secretin"
	Xue et al, Medline Abstract, Dig Dis Sci 38:344-352 (1993) "Characterization of secretin release in secretin cell-enriched preparation isolated from canine duodenal mucosa"

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)